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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/588,082

06/20/2007

Jens Fogh

FOGH 5A

4018

1444 7590 12/10/2009  
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EXAMINER

PAK, YONG D

ART UNIT

PAPER NUMBER

1652

MAIL DATE

DELIVERY MODE

12/10/2009

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>		<b>Applicant(s)</b>	
	10/588,082		FOGH ET AL.	
	<b>Examiner</b>		<b>Art Unit</b>	
	YONG D. PAK		1652	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 10 September 2009.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1,8,9,11-16 and 42-49 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,8,9,11-16 and 42-49 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                       | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____.                                     |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>9/10/09</u> .   | 6) <input type="checkbox"/> Other: _____.                         |

### **DETAILED ACTION**

This application is a 371 of PCT/DK05/00068.

The amendment filed on September 10, 2009, amending claims 1, 11, and 18, canceling claims 2, 7, 24, 32, 34, and 36-41 and adding claims 42-59, has been entered.

Claims 1, 8-9, 11-16, and 42-49 are pending and are under consideration.

### ***Election/Restrictions***

Applicant's election without traverse of Group I (claims 1-2, 7-9, 11-16, and 18) in the reply filed on December 17, 2008 is acknowledged.

### ***Information Disclosure Statement***

The information disclosure statement (IDS) submitted on September 10, 2009 is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

### ***Response to Arguments***

Applicant's amendment and arguments filed on September 10, 2009, have been fully considered and are deemed to be persuasive to overcome some of the rejections previously applied.

***Claim Objections***

In view of the amendment, the objections to claims 1-2, 7, and 18 have been **withdrawn**.

Claim 11 remains objected due missing conjunction between elements VII)-VIII) in claim 11.

Contrary applicant's argument, the missing conjunction has not been supplied to claim 11.

Appropriate correction is required.

***Claim Rejections - 35 USC § 112 – 2<sup>nd</sup> paragraph***

In view of the amendment, the rejection of claim 18 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention has been **withdrawn**.

***Claim Rejections - 35 USC § 112- 1<sup>st</sup> paragraph***

In view of the amendment, the rejection of claims 1-2, 7-9, 11-16, and 18 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement, has been **withdrawn**.

In view of the amendment, the rejection of claims 1-2, 7-9, 11-16, and 18 under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement, has been **withdrawn**.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –  
(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 8-9, 11-16, and 42-49 are rejected under 35 U.S.C. 102(b) as being anticipated by Fogh et al.

Claims 1, 8-9, 11-16, and 42-49 are drawn to a method for production of recombinant a recombinant human arylsulfatase A (rhASA) by continuously culturing a human cell producing rhASA in a system comprising a bio-reactor by concentrating the rhASA by tangential flow filtration, using a DEAE sepharose column, using hydrophobic interaction column, using tangential flow filtration, using a polishing step comprising cation and anion exchange columns, using a viral reduction filter, formulating the rhASA in a buffer which comprises using a detergent, and filling the rhASA into a container and freeze-drying the enzyme.

Fogh et al. (WO 02/098455 A2 – form PTO-1449) discloses a method for production of recombinant a recombinant human arylsulfatase A (rhASA) having 100% sequence identity to SEQ ID NO:2 or 3 of the instant invention by continuously culturing a human cell producing rhASA in a system for about 163 hours, which is about a week, comprising a bio-reactor by concentrating the rhASA by tangential flow filtration, using a DEAE sepharose column, using hydrophobic interaction column, using tangential flow filtration, using a polishing step comprising cation and anion exchange columns, using a viral reduction filter, formulating the rhASA in a buffer which comprises using a detergent (tween 80), and filling the rhASA into a container and freeze-drying the enzyme (pages 14-16 and 40-44 and Sequence Listing pages 1-3). Therefore, the reference of Fogh et al. anticipates claims 1, 8-9, 11-16, and 42-49.

In response to the previous Office Action, applicants have traversed the above rejection.

Applicants argue that Fogh et al. does not anticipate the instant claims because method of Fogh et al. is a batch process and not a continuous process. Claims 1, 8-9, 11-16, and 43-49 do not recite a limitation of the length of culturing a mammalian cell. Fogh et al. discloses a small scale and semi-large scale fermentation, both of which are cultured continuously for 163 hours, or about a week. Also, the purification method of Example 6 is for a large production, not purifying the combined “batches” of the small scale and semi-large scale product.

Applicants argue that Fogh et al. does not anticipate the instant claims because “cation exchange with salt gradient elution” appears to be active steps and not a

passive step. Examiner respectfully disagrees. The claims recite that a passive step is passage (loading and eluting) through a cation exchange chromatography resin or membrane, which Fogh et al. discloses on page 42.

Hence the rejection is maintained.

### ***Conclusion***

Claims 3 are rejected.

No claim is allowed.

### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Art Unit: 1652

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yong Pak whose telephone number is 571-272-0935. The examiner can normally be reached 6:30 A.M. to 5:00 P.M. Monday through Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll free).

/Yong D Pak/

Primary Examiner, Art Unit 1652